UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

CV 10 - 4248

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y
SEP 17 2010 ★
BROOKLYN OFFICE

CARYN BIENSTOCK,

Plaintiff,

- against -

ETHICON, INC., and
JOHNSON & JOHNSON, INC.,

Defendants.

Case No.

COMPLAINT AND DEMAND FOR JURY TRIAL

DEARIE, CH.J.

J. ORENSTEIN, M.J.

Plaintiff, by her attorneys, **THE LAW OFFICES OF SYBIL SHAINWALD, P.C.**, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION & VENUE

1. This Court has jurisdiction over this action pursuant to 28 United States Code § 1332, based upon diversity jurisdiction in that the Plaintiff is a citizen of a State different from the States where Defendants are incorporated and have their principal places of business, and because the amount in controversy exceeds seventy-five thousand dollars ($75,000.00).

THE PARTIES

2. The Plaintiff CARYN BIENSTOCK (hereinafter alternatively referred to as "the Plaintiff" or "Bienstock") is an individual and at all times relevant hereto was a domiciliary of the State of Connecticut.

3. Defendant JOHNSON & JOHNSON, INC., (hereinafter alternatively referred to as "the parent company") is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey.

4. Defendant ETHICON, INC., a subsidiary of Defendant JOHNSON & JOHNSON, INC., is a corporation existing under the laws of the State of New Jersey, with its principal place of business at Route 22 West, Somerville, New Jersey.

5. Defendants JOHNSON & JOHNSON, INC., and ETHICON, INC. will collectively be referred to as "Defendants."

6. At all relevant times, Defendants were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell, and/or distribute certain devices, collectively known as the Gynecare Prolift Pelvic Floor Repair System (hereinafter "the Prolift system" or "the system"), designed to treat pelvic organ prolapse via surgery.

7. The Defendants knew or should have known, that the system and its components had been insufficiently tested; that they were defectively created, designed, manufactured, tested, and formulated; lacked adequate warnings; and were negligently and recklessly advertised, marketed, promoted and sold.

8. The Defendants made certain claims that were distributed and circulated to the medical profession and to the general public through advertising, literature, brochures, and other materials stating that the system and its components were of a safe and efficacious material for use in surgeries related to pelvic organ prolapse.

9. At the time, the Defendants knew or should have known that the system and/or its components had the potential to become harmful to patients in whom the products were applied.

10. In seeking approval for the Prolift system from the United States Food and Drug Administration ("FDA") pursuant to section 510(k) of the Food, Drug, and Cosmetic Act, the Defendants submitted an application to said agency on June 4, 2007.

11. The FDA approved the Prolift system on May 15, 2008. However, on October 20, 2008, the FDA issued a public health notification alerting the medical community that transvaginal placement of mesh device systems, including Prolift, could lead to potentially serious complications including erosion of the material, infection, pain, urinary complications, and recurrence of prolapse or incontinence.

12. Upon information and belief, Defendants misrepresented the risks inherent in the use of the Prolift system in their applications to the FDA and to other governmental persons and/or agencies.

13. Defendants knew, or should have known, of the above-mentioned risks based upon the state of knowledge as it existed at that time and upon generally accepted engineering, medical and research standards and principles.

14. The Defendants, their agents, servants and/or employees manufactured, produced, promoted, formulated, created or designed the Prolift system without making proper and sufficient tests to determine the dangers and contra-indications thereof, and without warning the public and the medical profession of the inherent dangers, contra-indications, and side effects. The Defendants also negligently advertised and recommended the use of the system to the medical community without sufficient knowledge as to its dangerous propensities; represented that the system and its components were safe for use for their intended purpose when, in fact, they were unsafe; and failed to conduct sufficient testing programs to determine whether or not the system was safe for use.

15. The Defendants, their agents, servants and/or employees were careless and negligent in the manufacturing, selling, distribution, merchandising, advertising, promotion, compounding, packaging, fabrication, analyzing, marketing, and recommendation of said

products without making proper and sufficient tests to determine the dangers thereof.

16. On October 31, 2007, the Plaintiff underwent uterine prolapse surgery in which the Prolift system was used.

17. As a direct and proximate result of the Defendants' negligence, the mesh implanted into the Plaintiff's vagina during this initial surgery became exposed, requiring additional surgery on April 15, 2008, to excise this extraneous mesh.

18. As a further direct and proximate result of the Defendants' negligence, the Plaintiff underwent yet another surgical procedure on February 22, 2010, for further excision of exposed transvaginal mesh associated with the Prolift system.

19. By reason of the foregoing, Plaintiff CARYN BIENSTOCK suffered vaginal scarring, erosion of the vaginal walls, dyspareunia, painful and difficult bowel movements, and other serious and permanent injuries; required extensive hospitalizations, medical care, and surgeries; has been incapacitated from her normal functioning and will be unable to pursue normal means of livelihood; and has been otherwise grossly damaged.

FIRST CAUSE OF ACTION
(Negligence)

20. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "19" inclusive, as if expressly rewritten herein.

21. The negligence and carelessness of the Defendants, jointly, severally, acting in concert and via their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Designing, manufacturing, supplying, and distributing the Prolift system in a defective condition when they knew or should have known of said defects;

b. Failing to act reasonably to identify, eliminate, or reduce the risks of hazards associated with the intended and foreseeable uses of the system;

c. Failing to utilize existing technology or to apply established engineering, scientific, and medical principles to eliminate or reduce the risks and hazards associated with the intended and foreseeable uses of the system;

d. Designing, manufacturing, supplying, and distributing the system, which was unreasonably dangerous, unsafe, and defective with regard to all of its intended and foreseeable purposes and uses;

e. Designing, manufacturing, supplying, and distributing the system without proper safeguards, safety devices, safety appliances, and safety equipment;

f. Designing, manufacturing, supplying, and distributing the system, which was improper for the purpose(s) for which Defendants knew it would be used;

g. Designing, manufacturing, supplying and distributing the system without adequate warnings;

h. Negligently designing, manufacturing, supplying, and distributing the system;

i. Failing to advise Plaintiff's physician of the dangers associated with the use of the system;

j. Failing to advise Plaintiff of the dangers associated with the use of the system, which deprived her of an opportunity to man an informed choice with regard to the surgery;

k. Failing to comply with standards, specifications, and regulations in the industry;

l. Failing to comply with federal and state statutes and regulations;

m. Failing to adequately test the system or its components; and

n. Failing to conduct adequate post-marketing surveillance of the system.

22. As a direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff CARYN BIENSTOCK sustained permanent and severe personal injuries, including but not limited to vaginal scarring, erosion of the vaginal walls, dyspareunia, painful and difficult bowel movements, and other serious and permanent injuries.

23. As a direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff CARYN BIENSTOCK has in the past and will in the future incur extensive pain and suffering, mental anguish, and burdensome financial costs associated with medical care.

24. As a further direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff CARYN BIENSTOCK has been and will be disabled from performing her usual duties, activities, and occupations with a consequent loss of earnings and earning power.

25. By reason of the foregoing, Plaintiff CARYN BIENSTOCK has been damaged as against each Defendant in the sum of ONE MILLION DOLLARS ($1,000,000) in compensatory damages and ONE MILLION DOLLARS ($1,000,000) in punitive damages.

SECOND CAUSE OF ACTION
(Strict Products Liability)

26. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "25" inclusive, as if expressly rewritten herein.

27. Defendants, by and through their agents, servants, employees and/or ostensible agents are strictly liable to Plaintiff because at all times herein mentioned the Defendants manufactured, compounded, distributed, recommended, merchandized, advertised, promoted, sold, purchased, prescribed, and otherwise facilitated the Prolift system as hereinabove described in violation of applicable statutes, regulations and appropriate standards of care.

28. The Prolift system was expected to and did reach the usual consumers,

handlers, and persons coming into contact with such product and its components without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

29. At those times, the system and its components were in an unsafe, defective, and inherently dangerous condition, which was hazardous to users, the general public, and in particular the Plaintiff herein.

30. Defendants, while regularly engaged in the business activities aforementioned, did design, develop, manufacture, produce, test, sell, market, and/or distribute the Prolift system and its components, which were surgically applied to Plaintiff CARYN BIENSTOCK.

31. At all times herein mentioned, the system was in an unsafe and defective condition and Defendants, individually, jointly, and severally, knew or had reason to know that the Prolift system was defective and unsafe in violation of applicable statutes, regulations, and appropriate standards of care.

32. The Prolift system and its components were inherently dangerous.

33. At the time of Plaintiff's surgeries, the Prolift system and its components were being used for the purposes and in the manner Defendants intended.

34. By the exercise of reasonable care, Plaintiff could not have discovered the defects herein mentioned and/or perceived their danger.

35. As a direct and proximate result of the defective condition of the products manufactured and supplied by Defendants, Plaintiff was caused to sustain permanent and severe personal injuries, including but not limited to vaginal scarring, erosion of the vaginal walls, dyspareunia, painful and difficult bowel movements, and other serious and permanent injuries.

36. By reason of the foregoing, the Defendants are strictly liable in tort to the Plaintiff CARYN BIENSTOCK for the marketing of a defective product.

37. By reason of the foregoing, Plaintiff has been damaged as against each Defendant in the sum of ONE MILLION DOLLARS ($1,000,000) in compensatory damages and ONE MILLION DOLLARS ($1,000,000) in punitive damages.

THIRD CAUSE OF ACTION
(Breach of Implied Warranty)

38. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "37" inclusive, as if expressly rewritten herein.

39. In manufacturing, marketing, distributing, and selling the Prolift system, Defendants owed a duty to users, including Plaintiff CARYN BIENSTOCK, to provide products which were fit for the ordinary purpose for which they were used, and to ensure that the products conformed to the promises and affirmations made to the ultimate consumer, in this case Plaintiff CARYN BIENSTOCK.

40. Defendants knew or should have known that the general public and Plaintiff in particular relied on them to provide products which were fit for their ordinary or intended use and which would conform to the promises and affirmations concerning them.

41. Defendants impliedly warranted to Plaintiff that the Prolift system was safe and suitable for use, particularly in a surgical setting.

42. Defendants, as more specifically set forth above, breached their duties and implied warranty of merchantability.

43. As a direct and proximate result of the Defendants' breaches of their duties and implied warranties of merchantability, Plaintiff CARYN BIENSTOCK was caused to sustain severe and grievous personal injuries, including but not limited to vaginal scarring, erosion of the

vaginal walls, dyspareunia, painful and difficult bowel movements, and other serious and permanent injuries.

44. By reason of the foregoing, Plaintiff has been damaged as against each Defendant in the sum of ONE MILLION DOLLARS ($1,000,000) in compensatory damages and ONE MILLION DOLLARS ($1,000,000) in punitive damages.

FOURTH CAUSE OF ACTION
(Breach of Express Warranty)

45. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "44" inclusive, as if expressly rewritten herein.

46. Defendants expressly warranted that the Prolift system was safe and suitable for use as reinforcement for human tissue in certain types of surgery associated with pelvic organ prolapse.

47. The Prolift system failed to conform to the express warranties of the Defendants.

48. As a direct and proximate result of the Defendants' breaches of their duties and express warranties, Plaintiff CARYN BIENSTOCK was caused to sustain severe and grievous personal injuries, including but not limited to vaginal scarring, erosion of the vaginal walls, dyspareunia, painful and difficult bowel movements, and other severe and permanent injuries.

49. By reason of the foregoing, Plaintiff has been damaged as against each Defendant in the sum of ONE MILLION DOLLARS ($1,000,000) in compensatory damages and ONE MILLION DOLLARS ($1,000,000) in punitive damages.

FIFTH CAUSE OF ACTION
(Fraudulent Misrepresentation)

50. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "49" inclusive, as if expressly rewritten herein.

51. At all relevant times, Defendants jointly, severally, acting in concert, with or though others, their agents, servants, and/or employees made false and fraudulent representations to the medical community and eventual recipients of the Prolift system, including but not limited to representations that the system and its components had been tested and found to be safe and effective products for surgery related to pelvic organ prolapse.

52. Defendants knew or should have known these misrepresentations to be false. Nevertheless, Defendants willfully, wantonly, and recklessly disregarded the falsity of their statements; made representations fraudulently and deceitfully with the intent to induce women to seek surgical treatment involving the Prolift system, and did in fact induce them; and induced the medical community to recommend, dispense, purchase, and provide surgical treatment to these women. All of Defendants' above acts and/or omissions evince a callous, reckless, willful, and depraved indifference to the life, health, safety, and welfare of the system's intended recipients, including the Plaintiff herein.

53. At the time Defendants made their misrepresentations, recipients of the Prolift system, including Plaintiff CARYN BIENSTOCK, could not by the exercise of their own reasonable care discover the falsity of Defendants' misrepresentations and, instead, reasonably believed them to be true.

54. The Defendants sought and in fact did obtain FDA approval of the Prolift system in its defective form, based on Defendants' fraudulent misrepresentations, and Defendants inserted the system into the stream of commerce, causing harmful effects to recipients thereof. Defendants knew or should have known that the Prolift system had been insufficiently tested, lacked adequate warnings, and would lead to serious injury amongst its recipients. Defendants

thereby breached their duty to Plaintiff, other recipients of the system, and the medical community.

55. As a direct and proximate result of Defendants' fraudulent conduct and misrepresentations, made jointly, severally, acting in concert, with or though others, their agents, servants, and/or employees, Plaintiff CARYN BIENSTOCK suffered permanent, severe, and grievous personal injuries including but not limited to vaginal scarring, erosion of the vaginal walls, dyspareunia, painful and difficult bowel movements, and other serious and permanent injuries.

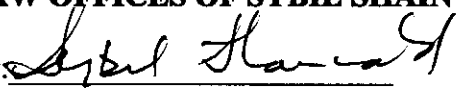
56. By reason of the foregoing, Plaintiff has been damaged as against each Defendant in the sum of ONE MILLION DOLLARS ($1,000,000) in compensatory damages and ONE MILLION DOLLARS ($1,000,000) in punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff CARYN BIENSTOCK demands judgment against each Defendant on each cause of action with interest together with the costs and disbursements of this action.

LAW OFFICES OF SYBIL SHAINWALD, P.C.

Dated: September 16, 2010

By: 

Sybil Shainwald (SS-1554)
200 West 57th Street, Suite 402
New York, New York 10019
(212) 425-5566

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

SYBIL SHAINWALD (SS-1554)

VERIFICATION

STATE OF NEW YORK)
s.s.:
COUNTY OF NEW YORK)

SYBIL SHAINWALD, an attorney and counselor at law, duly admitted to practice in the Courts of the State of New York and a member of the **LAW OFFICES OF SYBIL SHAINWALD, P.C.**, attorneys for Plaintiffs herein, duly affirms the following to be true under penalties of perjury:

I have read the foregoing **COMPLAINT AND DEMAND A JURY TRIAL** and know the contents thereof, and upon information and belief, I believe the matters alleged therein to be true.

The reason this Verification is made by deponent and not by the Plaintiffs is that Plaintiffs reside in a county other than the one in which your deponent's office is maintained.

The source of your deponent's information and the grounds of my belief are communications, papers, reports and investigations contained in my file.

Dated: New York, New York
September 16, 2010

Sybil Shainwald

SYBIL SHAINWALD, ESQ.